

age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.

## **PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

### **Subpart A—General Provisions**

Sec.

341.1 Scope.

341.3 Definitions.

### **Subpart B—Active Ingredients**

341.12 Antihistamine active ingredients.

341.14 Antitussive active ingredients.

341.16 Bronchodilator active ingredients.

341.18 Expectorant active ingredient.

341.20 Nasal decongestant active ingredients.

341.40 Permitted combinations of active ingredients.

### **Subpart C—Labeling**

341.70 Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product).

341.72 Labeling of antihistamine drug products.

341.74 Labeling of antitussive drug products.

341.76 Labeling of bronchodilator drug products.

341.78 Labeling of expectorant drug products.

341.80 Labeling of nasal decongestant drug products.

341.85 Labeling of permitted combinations of active ingredients.

341.90 Professional labeling.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

EDITORIAL NOTE: Nomenclature changes to part 341 appear at 69 FR 13717, Mar. 24, 2004.

### **Subpart A—General Provisions**

#### **§ 341.1 Scope.**

(a) An over-the-counter cold, cough, allergy, bronchodilator, or anti-asthmatic drug product in a form suitable for oral, inhalant, or topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the condi-

tions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[51 FR 35339, Oct. 2, 1986]

#### **§ 341.3 Definitions.**

As used in this part:

(a) *Bronchodilator drug.* A drug used to overcome spasms that cause narrowing of the bronchial air tubes, such as in the symptomatic treatment of the wheezing and shortness of breath of asthma.

(b) *Oral antitussive drug.* A drug that either is taken by mouth or is dissolved in the mouth in the form of a lozenge and acts systemically to relieve cough.

(c) *Topical antitussive drug.* A drug that relieves cough when inhaled after being applied topically to the throat or chest in the form of an ointment or from a steam vaporizer, or when dissolved in the mouth in the form of a lozenge for a local effect.

(d) *Expectorant drug.* A drug taken orally to promote or facilitate the removal of secretions from the respiratory airways.

(e) *Antihistamine drug.* A drug used for the relief of the symptoms of hay fever and upper respiratory allergies (allergic rhinitis).

(f) *Oral nasal decongestant drug.* A drug that is taken by mouth and acts systemically to reduce nasal congestion caused by acute or chronic rhinitis.

(g) *Topical nasal decongestant drug.* A drug that when applied topically inside the nose, in the form of drops, jellies, or sprays, or when inhaled intranasally reduces nasal congestion caused by acute or chronic rhinitis.

(h) *Calibrated dropper.* A dropper calibrated such that the volume error incurred in measuring any liquid does not exceed 15 percent under normal use conditions.

(i) *Effervescent dosage form.* A dosage form intended to be dissolved in water before administration. It contains, in addition to the active ingredient(s), mixtures of acids (citric acid, tartaric acid) and sodium bicarbonate, which

## Food and Drug Administration, HHS

## § 341.40

release carbon dioxide when dissolved in water.

[51 FR 35339, Oct. 2, 1986, as amended at 54 FR 8509, Feb. 28, 1989; 55 FR 40382, Oct. 3, 1990; 57 FR 58374, Dec. 9, 1992; 59 FR 43409, Aug. 23, 1994; 71 FR 43362, Aug. 1, 2006]

### Subpart B—Active Ingredients

#### § 341.12 Antihistamine active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient:

- (a) Brompheniramine maleate.
- (b) Chlorcyclizine hydrochloride.
- (c) Chlorpheniramine maleate.
- (d) Dexbrompheniramine maleate.
- (e) Dexchlorpheniramine maleate.
- (f) Diphenhydramine citrate.
- (g) Diphenhydramine hydrochloride.
- (h) Doxylamine succinate.
- (i) Phenindamine tartrate.
- (j) Pheniramine maleate.
- (k) Pyrilamine maleate.
- (l) Thonzylamine hydrochloride.
- (m) Triprolidine hydrochloride.

[57 FR 58374, Dec. 9, 1992, as amended at 59 FR 4218, Jan. 28, 1994]

#### § 341.14 Antitussive active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits and in the dosage forms established for each ingredient in § 341.74(d):

(a) *Oral antitussives*. (1) Chlophedianol hydrochloride.

(2) *Codeine ingredients*. The following ingredients may be used only in combination in accordance with § 290.2 and 21 CFR 1308.15(c).

- (i) Codeine.
- (ii) Codeine phosphate.
- (iii) Codeine sulfate.
- (3) Dextromethorphan.
- (4) Dextromethorphan hydrobromide.
- (5) Diphenhydramine citrate.
- (6) Diphenhydramine hydrochloride.
- (b) *Topical antitussives*. (1) Camphor.
- (2) Menthol.

[52 FR 30055, Aug. 12, 1987, as amended at 59 FR 29174, June 3, 1994; 67 FR 4907, Feb. 1, 2002]

#### § 341.16 Bronchodilator active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

- (a) Ephedrine.
- (b) Ephedrine hydrochloride.
- (c) Ephedrine sulfate.
- (d) Epinephrine.
- (e) Epinephrine bitartrate.
- (f) Racephedrine hydrochloride.
- (g) Racepinephrine hydrochloride.

[51 FR 35339, Oct. 2, 1986]

#### § 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in § 341.78(d).

[54 FR 8509, Feb. 28, 1989]

#### § 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient:

- (a) *Oral nasal decongestants*. (1) Phenylephrine hydrochloride.
- (2) Pseudoephedrine hydrochloride.
- (3) Pseudoephedrine sulfate.
- (4) Phenylephrine bitartrate in an effervescent dosage form.
- (b) *Topical nasal decongestants*. (1) Levmetamfetamine.
- (2) Ephedrine.
- (3) Ephedrine hydrochloride.
- (4) Ephedrine sulfate.
- (5) [Reserved]
- (6) Naphazoline hydrochloride.
- (7) Oxymetazoline hydrochloride.
- (8) Phenylephrine hydrochloride.
- (9) Propylhexedrine.
- (10) Xylometazoline hydrochloride.

[59 FR 43409, Aug. 23, 1994, as amended at 63 FR 40650, July 30, 1998; 71 FR 43362, Aug. 1, 2006]

#### § 341.40 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the dosage limits established in parts 341, 343, and 356 of this chapter and the product is labeled in accordance with §§ 341.70 or 341.85: